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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 70

Docket No. CDC-2012-0016

RIN 0920-AA22

Control of Communicable Diseases: Interstate; Scope and Definitions

AGENCY: Centers for Disease Control and Prevention (HHS/CDC), Department of Health and Human Services (HHS).

ACTION: Direct Final Rule and request for comments.

SUMMARY: In this Direct Final Rule, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is proposing to update the definitions for interstate quarantine regulations to reflect modern terminology and plain language used by private industry and public health partners. These updates will not affect current practices. As part of the update, we are updating two existing definitions and adding eight new definitions to clarify existing provisions, as well as updating regulations to reflect

the most recent Executive Order addressing quarantinable communicable diseases.

DATES: The DFR is effective on [INSERT 60 DAYS AFTER DATE OF PUBLICATION TO THE FEDERAL REGISTER] unless significant adverse comment is received by [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the Federal Register within 30 days after the comment period on this DFR ends. If we receive any timely significant adverse comment, we will withdraw this DFR in part or in whole by publication of a document in the Federal Register within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by "RIN 0920-AA22": by any of the following methods:

- Internet: Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-03, Atlanta, Georgia 30333, ATTN: Part 70 DFR.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant comments will be posted without change to <http://regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, please go to <http://www.regulations.gov>. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 1600 Clifton Road, N.E., Atlanta, Georgia 30333. Please call ahead to 1-866-694-4867 and ask for a representative in the Division of Global Migration and Quarantine (DGMQ) to schedule your visit. To download an electronic version of the rule, access <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For questions concerning this direct final rule: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop E-03, Atlanta, Georgia 30333; telephone 404-498-1600.

SUPPLEMENTARY INFORMATION

HHS/CDC is publishing a DFR because it does not expect to receive any significant adverse comments and believes that updating definitions to add clarity to the regulations is non-controversial. However, in this Federal Register, HHS/CDC is simultaneously publishing a companion notice of proposed rulemaking (NPRM) that proposes identical modifications. If HHS/CDC does not receive any significant adverse comments on this DFR within the specified comment period, we will publish a document in the Federal Register confirming the effective date of this final rule within 30 days after the comment period on the DFR ends and withdraw the NPRM. If HHS/CDC receives any timely significant adverse comment, we will withdraw the DFR in part or in whole by publication of a document in the Federal Register within 30 days after the comment period ends. HHS/CDC will carefully consider all public comments received before proceeding with any subsequent final rule based on the NPRM. A significant adverse comment is one that explains: (1) why the DFR is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the DFR will be ineffective or unacceptable without a change.

This preamble is organized as follows:

- I. Public Participation
- II. Authority for these Regulations
- III. Rationale for DFR

- IV. Updates to Section 70.1
 - A. Definitions Updated under Section 70.1
 - B. Definitions Added to Section 70.1
- V. Rationale for Updates under Section 70.6
- VI. Alternatives Considered
- VII. Required Regulatory Analyses
 - A. Required Regulatory Analyses under Executive Orders 12866 and 13563
 - B. Regulatory Flexibility Act
 - C. Small Business Regulatory Enforcement Fairness Act of 1996
 - D. The Paperwork Reduction Act of 1995
 - E. National Environmental Policy Act (NEPA)
 - F. Civil Justice Reform (Executive Order 12988)
 - G. Executive Order 13132 (Federalism)
 - H. Plain Language Act of 2010

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed publicly. Comments are invited on any topic related to this DFR.

II. Authority for these Regulations

The primary authority supporting this rulemaking is section 361 of the Public Health Service Act (42 U.S.C. 264). Section 361 authorizes the Secretary of HHS to make and enforce regulations as in the Secretary's judgment are necessary to prevent the

introduction, transmission, or spread of communicable diseases from foreign countries into the states or possessions of the United States and from one state or possession into any other state or possession. Regulations that implement federal quarantine authority are currently promulgated in 42 CFR Parts 70 and 71. Part 71 contains regulations to prevent the introduction, transmission, and spread of communicable diseases into the states and possessions of the United States, while Part 70 contains regulations to prevent the introduction, transmission, or spread of communicable diseases from one state into another. The Secretary has delegated to the Director of the Centers for Disease Control and Prevention the authority for implementing these regulations.

Authority for carrying out most of these functions has been delegated to HHS/CDC's Division of Global Migration and Quarantine (DGMQ). The Secretary's authority to apprehend, examine, detain, and conditionally release individuals is limited to those quarantinable communicable diseases published in an Executive Order of the President. This list currently includes cholera, diphtheria, infectious tuberculosis (TB), plague, smallpox, yellow fever, and viral hemorrhagic fevers, such as Marburg, Ebola, and Crimean-Congo hemorrhagic fever (CCHF), Severe Acute Respiratory Syndrome (SARS), and influenza caused by novel or re-emergent influenza viruses that are

causing or have the potential to cause a pandemic (see Executive Order 13295, as amended by Executive Order 13375 on April 1, 2005).

III. Rationale for DFR.

Through this DFR, HHS/CDC is updating definitions to Part 70 to reflect modern science and current practices. HHS/CDC has chosen to publish a DFR because we view this as a non-controversial action and anticipate no significant adverse comment. This DFR does not create any additional requirements or burden upon the regulated community, nor does it affect the current practices of HHS/CDC. A significant adverse comment is one that explains: (1) why the DFR is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the DFR will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of the DFR, HHS/CDC will consider whether it warrants a substantive response in a notice and comment process. If we receive significant adverse comment on this DFR, we will publish a timely withdrawal in the Federal Register informing the public that the amendment in this rule will not take effect. If this DFR is withdrawn, we will carefully consider all public comments before proceeding with any subsequent final rule based on the

NPRM which is being published simultaneously in the Federal Register.

IV. Updates to Section 70.1

Regulations that implement federal authority for interstate quarantine are currently promulgated in 42 CFR Part 70. The Secretary of HHS has delegated to the Director of the Centers for Disease Control and Prevention the authority for implementing 42 CFR Part 70.

Through this DFR, HHS/CDC proposes to update the Definitions for 42 CFR Part 70, under section 70.1, to reflect modern terminology and plain language commonly used by private sector industry and public health partners, as well as clarify the intent of the provisions that follow. Specifically, we are updating two existing definitions and adding eight new definitions to clarify existing provisions, as well as updating 70.6 to reflect the language of the most recent Executive Order concerning quarantinable communicable diseases.

Section 70.1 (b) contains the definitions used in this DFR. The DFR proposes new or updated definitions to be consistent with modern quarantine concepts and current medical and public health principles and practice. Table 1 lists the current definitions found in 42 CFR Part 70 and the definitions proposed in this DFR.

Table 1:

Definitions and Corresponding Changes in Definitions in the Final Rule	
Existing Definitions in 42 CFR Part 70	Corresponding, New or Updated Definition in DFR
	CDC
Communicable diseases	No Change
Communicable period	No Change
	Conditional release
Conveyance	No Change
	Director
Incubation period	No Change
Interstate traffic	No Change
	Isolation
	Master or Operator
Possession	Updated
	Quarantine
	Quarantinable communicable disease
State	Updated
	U.S Territory
Vessel	No Change

A. Definitions Updated under Section 70.1

Possession. To best add clarity to Part 70, we have updated the term "possession" to mean "U.S. Territory" and defined U.S. Territory to include American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. Currently, only Puerto Rico and the Virgin Islands are explicitly listed in the definition.

Thus, CDC is updating this provision to explicitly list the other U.S. jurisdictions to which this part applies.

State. To best add clarity to the regulations of Part 70, specifically where roles and responsibilities are outlined, we have included a definition of "state" to mean any of the 50 states within the United States, plus the District of Columbia.

B. Definitions Added to Section 70.1

CDC. We have defined "CDC" to mean the Centers for Disease Control and Prevention within the Department of Health and Human Services to clarify the provisions under Part 70.

Conditional release. We have defined "conditional release" to have the same meaning as "surveillance," as that term is defined in 42 CFR Part 71. We have included this definition to best add clarity to the provisions and practices under Part 70, specifically section 70.6, as well as to ensure that conditional release and surveillance are both used consistently in both Parts 70 and 71.

Director. To clarify the provisions under Part 70, we have defined "Director" to mean the Director, Centers for Disease

Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.

Isolation. In this DFR, "isolation" is defined as the separation of an individual or group reasonably believed to be infected with a quarantinable communicable disease from those who are healthy to prevent the spread of the quarantinable communicable disease. This DFR clarifies the distinction between quarantine and isolation by separately defining "quarantine" and "isolation" to distinguish these common public health measures. Isolation, as currently used in 42 CFR 71.1, applies to both persons and groups of persons. Thus, CDC is changing the definition in Part 70 so that the term is used consistently in both Part 70 and 71. Applying isolation measures to groups of individuals is consistent with CDC's current practice and does not constitute a substantive change.

Master or Operator. This DFR defines "Master" or "Operator" as the aircrew or sea crew member with responsibility respectively for aircraft or vessel operation and navigation or a similar individual with responsibility for a conveyance. We have included this definition to better identify and assign

responsibilities under this subpart (according to current practices).

Quarantine. This DFR defines "quarantine" as the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease. In this DFR, HHS/CDC is separately defining quarantine and isolation to distinguish these common public health measures. Applying quarantine measures to groups of individuals is consistent with HHS/CDC's current practice and does not constitute a substantive change.

Quarantinable communicable disease. Under this DFR, "quarantinable communicable disease" means any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act (42 U.S.C. 264). Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be found at <http://www.cdc.gov/quarantine> and in the docket as supplemental documents. If this Executive Order is amended,

HHS/CDC will enforce the amended order immediately and update its website. The definition for "quarantinable communicable disease" is being added to Part 70 through this DFR to reflect the most recent Executive Order regarding quarantinable communicable disease. This addition does not reflect a substantive change from current practice.

U.S. Territory. Under this DFR, "U.S. Territory" means any territory (also known as possessions) of the United States including American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. The Department of the Interior's Office of Insular Affairs, the federal government's cognizant agency for U.S. territories, no longer uses the term "possession" to refer to these jurisdictions. Consequently, HHS/CDC is adding a new definition for U.S. territory consistent with current federal usage.

V. Updates to Section 70.6

Section 70.6, *Apprehension and detention of persons with specific diseases*, contains the general authority for the Director to take measures with respect to persons to protect the public's health against the spread of communicable diseases "listed in an Executive Order setting out a list of

quarantinable communicable diseases, as provided under section 361(b) of the Public Health Service Act." The current section 71.32(a) lists Executive Order 13295, of April 4, 2003. The subpart states that "If this Order is amended, HHS will enforce that amended order." On April 1, 2005, this Executive Order was amended by Executive Order 13375. Therefore, as part of the non-controversial changes in this DFR, we are also updating section 70.6 to reflect the most recent amendment to the Executive Order which lists the "quarantinable communicable disease", which we have also defined. These changes are not substantive and will not affect current practices.

VI. Alternatives Considered.

Under Executive Order 13563 agencies are asked to consider all feasible alternatives to current practice and the rule as proposed. HHS/CDC notes that the main impact of this proposed rule is to update current definitions and clarify language in the current regulation to reflect modern terminology and plain language commonly used by global private sector industry and public health partners. The intent of these updates is to clarify the provisions of the existing regulation to help the regulated community comply with current regulation and protect public health. HHS/CDC believes that this rulemaking complies with the spirit of the Executive Order; updating current

definitions, clarifying language, and updating the referenced Executive Order provides good alternatives to the current regulation.

VII. Required Regulatory Analyses

A. Required Regulatory Analyses under Executive Orders 12866 and 13563

Under Executive Order 12866 (EO 12866), Regulatory Planning and Review (58 FR 51735, October 4, 1993) HHS/CDC is required to determine whether this regulatory action would be "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Orders. This order defines "significant regulatory action" as any regulatory action that is likely to result in a rule that may:

- Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients; or,
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in EO 12866.

Executive Order 13563 (EO 13563), Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011), updates some of the provisions of EO 12866 in order to promote more streamlined regulatory actions. This EO charges, in part, that, while protecting "public health, welfare, safety, and our environment" that regulations must also "promote predictability and reduce uncertainty" in order to promote economic growth. Further, regulations must be written in common language and be easy to understand. In the spirit of EO 13563, this DFR enhances definitions related to the control of communicable diseases and add more current medical terminology where appropriate.

HHS/CDC has determined that this DFR is simply an update and clarification of definitions and terms used in the current regulation. As such, the DFR complies with the spirit of EO 13563. Further, HHS/CDC has determined that this DFR is not a significant regulatory action as defined in EO 12866 because the

DFR is definitional and does not change the baseline costs for any of the primary stakeholders.

B. Regulatory Flexibility Act

We have examined the impacts of the rule under the Regulatory Flexibility Act (5 U.S.C. 601-612). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

C. Small Business Regulatory Enforcement Fairness Act of 1996

This DFR is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment,

investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. The Paperwork Reduction Act of 1995

HHS/CDC has already determined that the Paperwork Reduction Act applies to the data collection and record keeping requirements of 42 CFR Part 70 and has obtained approval by the Office of Management and Budget (OMB) to collect data and require record keeping under OMB Control No. 0920-0488, expiration 03/31/2013. The changes in this rule do not impact the data collection or record keeping requirements and do not require revision to the approval from OMB.

E. National Environmental Policy Act (NEPA)

Pursuant to 48 FR 9374 (list of HHS/CDC program actions that are categorically excluded from the NEPA environmental review process), HHS/CDC has determined that this action does not qualify for a categorical exclusion. In the absence of an applicable categorical exclusion, the Director, CDC, has determined that provisions amending 42 CFR Part 70 will not have a significant impact on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

F. Civil Justice Reform (Executive Order 12988)

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

G. Executive Order 13132 (Federalism)

HHS/CDC has reviewed this rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Plain Language Act of 2010

Under Public Law 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act and requests public comment on this effort.

List of Subjects in Part 70

Communicable diseases, Isolation, Public health, Quarantine, Quarantinable Communicable Disease.

Amended Text

For the reasons discussed in the preamble, the Centers for Disease Control and Prevention amends 42 CFR Part 70 as follows:

PART 70—INTERSTATE QUARANTINE

1. The authority citation for part 70 continues to read as follows:

AUTHORITY: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); section 361-369, PHS Act, as amended (42 U.S.C. 264-272); 31 U.S.C. 9701.

2. Amend §70.1 as follows:

a. Remove paragraph designations (a), (b), (c), (d), (e), (f), and (g).

b. Add in alphabetical order definitions of CDC, Conditional release, Director, Isolation, Master or Operator, Quarantine, Quarantinable communicable disease, and U.S Territory.

c. Revise the definitions of Possession and State.

The revisions and additions read as follows:

§70.1 General definitions.

* * * * *

CDC means the Centers for Disease Control and Prevention, Department of Health and Human Services.

* * * * *

Conditional release means "surveillance" as that term is defined in 42 CFR 71.1.

* * * * *

Director means the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.

* * * * *

Isolation means the separation of an individual or group reasonably believed to be infected with a quarantinable

communicable disease from those who are healthy to prevent the spread of the quarantinable communicable disease.

Master or Operator means the aircrew or sea crew member with responsibility respectively for aircraft or vessel operation and navigation, or a similar individual with responsibility for a conveyance.

Possession means U.S Territory.

Quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who are not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

Quarantinable communicable disease means any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act. Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov> and http://www.archives.gov/federal_register. If this Order is amended, HHS will enforce that amended order immediately and update that website.

State means any of the 50 states, plus the District of Columbia.

U.S Territory means any territory (also known as possessions) of the United States, including American Samoa, Guam, the Northern

Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

* * * * *

3. Revise § 70.6 to read as follows:

§ 70.6 Apprehension and detention of persons with specific diseases.

Regulations prescribed in this part authorize the detention, isolation, quarantine, or conditional release of individuals, for the purpose of preventing the introduction, transmission, and spread of the communicable diseases listed in an Executive Order setting out a list of quarantinable communicable diseases, as provided under section 361(b) of the Public Health Service Act. Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at <http://www.cdc.gov/quarantine> and http://www.archives.gov/federal_register. If this Order is amended, HHS will enforce that amended order immediately and update its website.

Date: December 13, 2012

Kathleen Sebelius

Secretary,

Department of Health and Human
Services.

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